## REMARKS

Applicants respectfully request entry of the amendments and remarks submitted herein. Claims 28 and 29 have been canceled without prejudice to continued prosecution. Therefore, claims 1-5 and 27 are currently pending, and claims 6-8 and 20-26 are withdrawn. Reconsideration of the pending application is respectfully requested.

### The 35 U.S.C. §112 Rejections

Claims 1-5 and 27-29 stand rejected under 35 U.S.C. 112, first paragraph, as the Examiner asserted that those claims lack written description. The Examiner asserted that immunogenicity is a physical property of a polypeptide and is not a functional property as Applicants had previously argued. Also, according to the Examiner, Applicants did not demonstrate a nexus between the fact pattern in the present application and the case law discussed in the Response dated July 5, 2006 (e.g., *Capon*, *Invitrogen*, and *Falkner*). Applicants respectfully traverse this rejection.

Whether or not the ability of a polypeptide to be recognized and bound by an antibody is considered a physical property or a functional property of that polypeptide, the claims are only directed toward those polypeptides that elicit an antibody response. Therefore, this language serves to limit the claims to only those polypeptides that exhibit this property, whether the property is considered a functional, physical or other type of property. In addition, the specification discloses how to obtain and identify immunogenic polypeptides. See, for example, page 20, lines 22-31 of the specification. Further, the specification exemplifies a number of different immunogenic polypeptides of a variety of different lengths including 7, 9, 12 and 15 residues in length. See, for example, page 29, lines 1-7; page 31, lines 19-25; page 34, line 20 – page 35, line 20; page 37, line 13 – page 38, line 5; page 40, lines 6-7; page 41, lines 15-17; and page 49, lines 3-5 of the specification. Therefore, Applicants were clearly in possession of the genus of immunogenic polypeptides at the time the application was filed.

Also, the Examiner stated that the specification has written description for claims directed toward immunogenic polypeptides *consisting of* 8 or 12 amino acids but not for immunogenic polypeptides *comprising* 8 or 12 amino acids. The Examiner is not applying the correct standard for written description. Applicants respectfully refer the Examiner to *Ex parte*

*Fisher* (72 USPQ2d 1020 (BPAI 2004)), which stated "that the claimed nucleic acid molecules may have other molecules attached to either or both of their 5' or 3' ends does not diminish appellants' adequate written description of the nucleic acid molecules." Also, *Ex parte Fisher* stated that "Applicants have provided the nucleotide sequences required by the claims...and have thus established possession of the claimed invention. The fact that the claims at issue are intended to cover molecules that include the recited sequences joined with additional sequences does not mean that applicants were any less in possession of the claimed nucleic acid molecules."

In addition, the current case law indicates that an Applicant can show possession of the claimed invention by describing the claimed invention using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997). Possession may be shown in a variety of ways including description of an actual reduction to practice, or by ... the disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that the Applicant was in possession of the claimed invention. See, e.g., *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 68, 119 S.Ct. 304, 312, 48 USPQ2d 1641, 1647 (1998); and *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406. As indicated above, Applicants' disclosure reduced to practice at least five different immunogenic polypeptides of 7, 9, 12 and 15 residues in length. See, for example, the references in the specification to SEQ ID NOs: 34, 36, 39, 40 and 41.

Applicants also reiterate the arguments concerning *Capon*, *Invitrogen* and *Falkner* from the July 5, 2006 Response to Office Action. The nexus between *Capon*, *Invitrogen* and *Falkner* and the present application is as follows. The *Capon*, *Invitrogen* and *Falkner* case law indicate that the amount of knowledge in the art has a direct effect on the amount of written description that is required to support a claim. In addition to Applicants' disclosure of a number of different species of varying length as well as disclosure with respect to identifying additional species, the knowledge in the art is very high as those of skill in the art can readily identify immunogenic polypeptides or which portions of a polypeptide are immunogenic. As evidence of the knowledge in the art, the prior art is replete with references in which the immunogenic portions of a polypeptide have been identified. By way of example only, see He et al., 2003, *Vaccine*,

21:4421-9; Soares & Rodrigues, 2002, *Parasitology*, 124:237-46; Gill et al., 1997, *Biochem. Soc. Trans.*, 25:281S). Therefore, in view of Applicants disclosure as well as the knowledge in the art regarding identifying which portions of a polypeptide are immunogenic, the current case law supports Applicants' arguments that the specification provides adequate written description for the pending claims.

In view of the remarks herein, Applicants respectfully request that the rejection of claims 1-5 and 27-29 under 35 U.S.C. 112, first paragraph, be withdrawn.

Claims 1-5 and 27-29 stand rejected under 35 U.S.C. 112, first paragraph, as the Examiner asserted that those claims lack enablement for their full scope. According to the Examiner, it is appropriate to maintain the rejection because the screening assays suggested by Applicant do not enable the claimed invention. To support this argument, the Examiner cites *Rochester v. Searle* and asserted that the Courts found that screening assays are not sufficient to enable an invention since they are merely a wish or plan for obtaining the invention. Applicants respectfully traverse this rejection.

Applicants respectfully submit that the Examiner is misinterpreting the *Rochester v. Searle* case. First, *Rochester v. Searle* is directed toward a written description issue and not an enablement issue. Second, the University of Rochester held claims directed toward methods of screening for compounds that selectively inhibited COX-1, and the Court determined that their patents did not contain adequate written description such that Searle's and a number of additional defendants' COX-2 inhibitors, Celebrex® and Bextra®, infringed the University of Rochester's claims directed toward methods of screening for compounds that specifically inhibit COX-2. Applicants submit that the relevance between the *Rochester v. Searle* case and the current enablement rejection against the pending claims is not clear. It is noted for the Examiner's convenience that Applicants' arguments referring to screening assays in the Response dated July 5, 2006 were with respect to the amount of experimentation that would be required by those of skill in the art to identify the claimed immunogenic polypeptides. Applicants respectfully refer the Examiner to *Hybritech Inc. v. Monoclonal Antibodies, Inc.* cited in the previous Response.

The Examiner states that "[s]ince the making of the broadly claimed invention is not enabled, one would not know how to use the broadly claimed invention." Office Action at page

6. Applicants respectfully submit that this statement is entirely incorrect. Applicants have indicated above that those of skill in the art would know how to identify those polypeptides that are immunogenic. Also, those of skill in the art would know how to use or what to do with immunogenic polypeptides once identified. See, for example, page 20, line 10 – page 22, line 10; and page 50, line 23 – page 52, line 5 of the present specification for representative disclosure regarding uses for the claimed immunogenic polypeptides.

The test for enablement is whether one skilled in the art at the time Applicants filed the present application could make or use the claimed invention from the disclosures in the specification coupled with the information known in the art without "undue" experimentation. See, *e.g.*, MPEP 2164.01. The factual considerations that must be weighed when determining whether "undue" experimentation would be required include: (1) the breadth of the claims, (2) the nature of the invention, (3) the state of the prior art, (4) the relative skill of those in the art, (5) the predictability or unpredictability of the art, (6) the amount of direction or guidance provided, (7) the presence or absence of working examples, and (8) the quantity of experimentation necessary. See, *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

Based on the 'Wands factors' and consideration of the evidence as a whole, the pending claims are fully enabled by the present specification. Again, *Hybritech Inc. v. Monoclonal Antibodies, Inc.* cited in the previous Response is relevant to the amount of experimentation that is considered to be undue. *Hybritech Inc. v. Monoclonal Antibodies, Inc.* stands for the proposition that even a large amount of experimentation is not undue if that experimentation is routine. The pending claims are enabled and, in view of the amendments and remarks herein, Applicants respectfully request that the rejection of claims 1-5 and 27-29 under 35 U.S.C. 112, first paragraph, be withdrawn.

Claims 28-29 stand rejected under 35 U.S.C. §112, first paragraph, as the Examiner asserted that those claims fail to comply with the written description requirement. According to the Examiner, the subject matter of claims 28 and 29 is new matter because there is no clear support in the specification or the claims as originally filed for such claims.

Although Applicants disagree with this rejection and submit that the specification does have support for claims 28 and 29, Applicants have canceled claims 28 and 29 without prejudice to continued prosecution in order to expedite prosecution. In view of the cancellation of claims 28 and 29, Applicants respectfully submit that the rejection of claims 28 and 29 under 35 U.S.C. §112, first paragraph, is moot.

The 35 U.S.C. §102 Rejections

Claims 1-5 and 27 stand rejected under 35 U.S.C. §102(b) as being anticipated by database Uniprot_03, Accession number Q9KGX7 or Q9KGX9. According to the Examiner, Applicant is arguing limitations that are not recited in the current claims. Applicants' arguments were based on the fact that the cited reference does not disclose a 'purified' polypeptide. This rejection is respectfully traversed.

Claim 1 is the only pending independent claim and is directed toward a "purified" immunogenic polypeptide. All of the remaining claims depend, either directly or indirectly, from claim 1. Therefore, all the pending claims require a "purified" immunogenic polypeptide. The reference cited by the Examiner does not describe a purified polypeptide, does not describe methods for purifying polypeptides, and does not teach or suggest that the polypeptide can be purified. The rejection of the pending claims as being *anticipated* by the cited reference is improper, and Applicants respectfully request that the rejection of claims 1-5 and 27 under 35 U.S.C. §102 be withdrawn.

Claims 1-5 and 27-29 stand rejected under 35 U.S.C. §102(b) as being anticipated by Zhang et al. (1995, *Infect. Immun.*, 63:1013-1019). According to the Examiner, Applicants' previous arguments regarding 'purified' are not correct, as Zhang et al. discloses purification of the claimed polypeptide. The Examiner points to the second paragraph in the right hand column of page 1014 of Zhang et al. Applicants respectfully traverse this rejection.

Zhang et al. purified P97 as well as a general population of adhesin polypeptides for comparison purposes. In addition to the first two full paragraphs in the right-hand column on page 1014, see also the 'Affinity chromatography' and 'Tryptic digestion of purified adhesins' section of the Results (pages 1014-1015). Simply based on this vague description of the

purification, the Examiner is asserting that one or more of the claimed polypeptides comprising at least eight consecutive residues of SEQ ID NO:8 are in the population of polypeptides purified by Zhang et al. The Examiner has provided no specific support for this assertion, and Applicants can find no disclosure in Zhang et al. regarding a purified immunogenic polypeptide that includes any portion of the sequence shown in SEQ ID NO:8. In view of the amendments and remarks herein, Applicants respectfully request that the rejection of claims 1-5 and 27-29 under 35 U.S.C. §102 be withdrawn.

Request for Rejoinder

Claims 6-8 and 20-26 were withdrawn as directed to non-elected species following the Restriction Requirement of July 6, 2005, and Applicant's election of September 28, 2005. The Examiner indicated in the Restriction Requirement, however, that the (elected) claims of Group I (claims 1-5 and 27) are related to the claims of Group III (claims 6-8) and Group V (claims 20-26) as product and process of use. Since non-elected claims 6-8 and 20-26 depend either directly or indirectly from claim 1, Applicants respectfully requests that claims 6-8 and 20-26 be rejoined pursuant to MPEP §821.04.

CONCLUSION

Applicants respectfully request that claims 1-8 and 20-27 be allowed. Please apply any charges or credits to Deposit Account No. 06-1050.

Respectfully submitted,

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